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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/779,457      | 01/07/1997  | PAUL J. CARTER       | P0986P2             | 5894             |

7590 12/03/2003

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| EXAMINER |
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BELYAVSKYI, MICHAIL A

|          |              |
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| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/779,457

Applicant(s)

CARTER ET AL.

Examiner

Michail A Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 12 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11, 12, 22 and 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/07/2003 has been entered.

Claims 1-8, 11-12 and 22-29 are pending.

Claims 23 and 24 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

*Claims 1-8, 11, 12, 22 and 25-29 are under consideration in the instant application.*

2. The filing date of the instant claims is the filing date of the instant applications, i.e. 01/07/1997, as the previous priority applications 08/667,197 and 08/585,005 do not support the claimed limitations of the instant application, encompassing a method for identifying an antibody recited in claims 1-8, 11,12, 22 and 25-29.

3. Claim12 is objected to because of the following informalities: the word "the" in the second line is misspelled . Appropriate correction is required.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-8, 11, 12, 22 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US. Patent 5,972,621 in view of Harlow et al (Antibodies, A Laboratory manual, 1988, Cold Spring Harbor)

For examination purposes it is noted that SEQ ID NO:2 of the instant application, coding human receptor variant 13.2 having a WSX motif is 100 % identical to Ob/leptin receptor (ObR), SEQ ID NO:4 taught by US Patent '621.

US Patent '621 teaches a method for identifying antibody which decrease body weight in animals, by specifically binding to extracellular domain of ObR (see entire document, Abstract, column 5, lines 44-60, column 6, lines 50-55 and column 8, lines 22-25 in particular). The method of identifying antibody comprises producing antibody, testing and identifying antibody that have an ability to decrease body weight (see column 22-23 in particular). US Patent '621 teaches a method of identifying antibodies that can be used in the detection and screening of the ObR in a biological samples, using immunoprecipitation and immunoblotting techniques (see column 22 in particular). US Patent '621 teaches a method for identifying antibody which decrease body weight in obese animals, wherein the obese animal is *ob/ob* mice (column 2, lines 39-48 in particular). US Patent '621 teaches a method for identifying antibody which decrease body weight in obese animals, wherein said antibody specifically bind to human receptor ObR (see column 22, lines 43-45 in particular). US Patent '621 teaches that said antibody is monoclonal or fragment wherein said fragment is  $F(ab')_2$  (column 22, lines 16-25 in particular), or human antibody, or humanized or antibody that also bind to a murine ObR receptor (column 23, lines 12-24 in particular).

US Patent '621 does not teach selecting agonist antibody with a particular affinity with a  $K_d$  of no more than  $1 \times 10^{-7}$  M.

Harlow et al., teaches that typical affinity values for antibodies used in immunoprecipitation and immunoblotting is in the range between  $10^{-7}$  M and  $10^{-9}$  M.

It is clear that both the prior art and applicant use the same method for identifying an agonist WSX receptor antibody and use the same treatment to achieve the same results. The claimed binding affinity of no more than about  $10^{-7}$  M is within the range between  $10^{-7}$  M and  $10^{-9}$  M, for antibodies used in immunoprecipitation and immunoblotting as taught by Harlow et al. Thus the referenced antibody taught by US Patent '621 would obviously have binding affinity with a  $K_d$  of no more than  $1 \times 10^{-7}$  M in the absence of a showing of unobvious property. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

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Claims 4-5 and 7-9 are included because both the reference method of identifying an antibody and the claimed method of identifying an antibody were using the same antigen to produced antibody. Therefore, the reference antibody would obviously bind to receptor having WSX motif within SEQ ID NO2 with same  $K_d$  and have the same IC50 in a KIRA ELISA in the absent a showing of unobvious property.

Claims 10-12 are included because the reference antibodies that specifically binding to extracellular domain of ObR would obviously have biological characteristics of an antibodies of the instant claims.

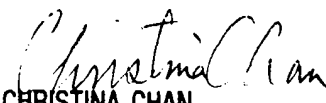
Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.  
Patent Examiner  
Technology Center 1600  
December 1, 2003

  
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